UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, et al. Plaintiffs, v. ANCHEN PHARMACEUTICALS INC., Defendant.	Civil Action No. 11-2317 (JAP) Consolidated for discovery purposes with: Civil Action Nos. 11-6348, 11-4275,13-0091 **OPINION**

PISANO, District Judge

In this Hatch-Waxman patent infringement action, Defendant Anchen Pharmaceuticals Inc. ("Defendant") moves under Federal Rule of Civil Procedure 12(b)(1) to dismiss the complaint filed by plaintiffs AstraZeneca AB, AstraZeneca LP, KBI-E Inc., and Pozen Inc. (collectively, "Plaintiffs") for lack of subject matter jurisdiction. Specifically, Defendant asserts that Plaintiffs' claims have been rendered moot, and that the matter should be dismissed without prejudice. The Court decides the matter without oral argument pursuant to Federal Rule of Civil Procedure 78 and Local Civil Rule 78.1. For the reasons below, Defendant's motion is granted.

I. BACKGROUND

In September of 2011, Defendant provided notice to Plaintiffs that it had filed Abbreviated New Drug Application ("ANDA") No. 202767 with the United States Food and

Drug Administration ("FDA") under 21 U.S.C. § 355(j) to obtain FDA approval to commercially manufacture, use, import, offer for sale, and sell in the United States certain dosages of naproxen and esomeprazole magnesium delayed release tablets, which are generic versions of Plaintiffs' drug product Vimovo. The Orange Book (the FDA's manual of *Approved Drug Products with Therapeutic Equivalence Evaluations*) lists seven patents as covering Vimovo. In its ANDA filing, Anchen included certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (*i.e.*, "Paragraph IV" certifications) as to five of these patents: U.S. Patent Nos. 5,900,424 ("the '424 patent"); 6,369,085 ("the '085 patent"); 6,926,907 ("the '907 patent"); 7,411,070 ("the '070 patent"); and 7,745,466 ("the '466 patent"). Defendant filed certifications under § 355(j)(2)(A)(vii)(III) (*i.e.*, "Paragraph III certifications") as to the other two patents. On October 28, 2011, Plaintiff filed its complaint in this matter alleging that by virtue of Defendant's ANDA filing, Defendant had infringed the '085, '907, '070, and '466 patents.

Two years later, on October 4, 2013, Defendant submitted documentation to FDA amending its Paragraph IV certifications for the '424, '085, '907, '070, and '466 patents. *See* Declaration of Sean Kelly, Ex. 3. Consequently, Defendant has certified to FDA that it is no longer seeking approval of its ANDA prior to the expiration dates of these patents. Defendants notified Plaintiffs of their amendment, and provided copies of the amended certification as well as a form stipulation of dismissal. Plaintiffs, however, refused to dismiss their claims. This motion followed.

II. ANALYSIS

A. Hatch-Waxman Framework

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the FDA is authorized to regulate the manufacture, distribution, and sale of drugs in the United States. In accordance with the FDCA, pharmaceutical companies seeking to market new drugs (often referred to as "pioneer" or "branded" drugs) must first obtain FDA approval by filing a new drug application ("NDA") containing extensive scientific data demonstrating the safety and effectiveness of the drug. 21 U.S.C. §§ 355(a), (b). An NDA applicant must also submit information on any patent that claims the drug, or a method of using the drug, and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. 21 U.S.C. §§ 355(b)(1), (c)(2). The FDA publishes this patent information in the "*Approved Drug Products with Therapeutic Equivalence Evaluations*" list, commonly known as the "Orange Book." *Id.*; *see also* 21 C.F.R. § 314.53(e).

The approval of generic drugs is governed by the FDCA as modified by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act"), codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271, and 282. These amendments were designed to balance the interests of encouraging innovation in the development of new drugs and accelerating the availability of lower-cost generic alternatives to branded drugs.

Under the Hatch-Waxman Act, a manufacturer submits an ANDA requesting approval of a generic version of an approved drug product. 21 U.S.C. § 355(j). The ANDA must include, among other things, data showing that the generic drug product is the bioequivalent to the branded drug product. 21 U.S.C. § § 355(j)(2)(A)(iv); (j)(4)(F). With respect to Orange Book listed patents for the branded drug, the Act requires each ANDA applicant to

submit one of four certifications: (1) the Orange Book contains no patent information relevant to their ANDA ("Paragraph I certification"), (2) the listed patents have expired ("Paragraph II certification"), (3) the applicant will not enter the market until the listed patents expire ("Paragraph III certification"), or (4) the applicant believes that the listed patents are invalid or will not be infringed by the applicant's generic compositions ("Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV). This certification is typically referred to as a "Paragraph I," "Paragraph II," "Paragraph III," or "Paragraph IV" certification.

An applicant wishing to challenge the validity of a patent or to claim that the patent would not be infringed by the product covered by the ANDA submits a Paragraph IV certification. An applicant files a Paragraph IV certification if the applicant believes "to the best of his knowledge ... that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted[.]" 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Under the Hatch-Waxman Act, a drug patent owner is permitted to bring an action for infringement in response to the filing of a Paragraph IV certification. *See* 35 U.S.C.A. § 271(e)(2)(A). Specifically,

> [i]t shall be an act of infringement to submit … an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act … for a drug claimed in a patent or the use of which is claimed in a patent … if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug … claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2). The Supreme Court has described § 271(e)(2) as creating "a highly artificial act of infringement" that is triggered upon submission of an ANDA containing an erroneous Paragraph IV certification. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678, 110 S. Ct. 2683, 110 L. Ed.2d 605 (1990).

Although Defendant originally submitted its ANDA with Paragraph IV certifications with respect to the above-mentioned five patents, Defendant has amended these certifications to Paragraph III certifications. As such, Defendant has now certified to FDA that it will only market its ANDA product after expiration of the '424, '085, '907, '070, '466 patents. Defendant asserts, therefore, that no case or controversy exists between the parties and the instant action should be dismissed without prejudice.

B. Legal Standard

Defendant brings its motion under Federal Rule of Civil Procedure 12(b)(1). Pursuant to Rule 12(b)(1), a case may be dismissed for "lack of subject-matter jurisdiction." Challenges to jurisdiction under Rule 12(b)(1) may be either facial or factual. *Petruska v. Gannon Univ.*, 462 F.3d 294, 302 n. 3 (3d Cir.2006), cert. denied, 550 U.S. 903, 127 S.Ct. 2098, 167 L.Ed.2d 813 (2007). A facial attack challenges the sufficiency of the pleadings, and the trial court "must consider the allegations of the complaint as true." *Id.* However, in a factual attack, plaintiff's allegations are afforded no presumption of truthfulness, *id.*, and the trial court may review evidence outside the pleadings. *Gould Electronics Inc. v. United States*, 220 F.3d 169, 176 (3d Cir.2000). The plaintiff bears the burden of establishing that jurisdiction exists. *Petruska*, 462 F.3d at 302 n. 3.

The jurisdiction of the federal courts is limited by Article III, § 2, of the Constitution to "Cases" and "Controversies." Article III restricts the authority of federal courts to resolving "'the legal rights of litigants in actual controversies.'" *Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 471, 102 S.Ct. 752, 70 L.Ed.2d 700 (1982). Notably, the "case-or-controversy" requirement exists at all stages of a case. "[A]n actual controversy must be extant at all stages of review, not

merely at the time the complaint is filed." *Genesis Healthcare Corp. v. Symczyk*, 133 S.Ct. 1523, 1528 (2013).

A case becomes moot if the "issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." *Murphy v. Hunt*, 455 U.S. 478, 481, 102 S. Ct. 1181, 71 L.Ed.2d 353 (1982); *see also Lewis v. Continental Bank Corp.*, 494 U.S. 472, 477-78, 110 S. Ct. 1249, 108 L.Ed.2d 400 (1990). Mootness occurs if (1) it can be said with assurance that there is no reasonable expectation that the alleged violation will recur, and (2) interim relief or events have completely and irrevocably eradicated the effects of the alleged violation. *County of Los Angeles v. Davis*, 440 U.S. 625, 631, 99 S.Ct. 1379, 1383, 59 L.Ed.2d 642 (1979).

Defendant argues that as a result of the amendment of its Paragraph IV certifications to Paragraph III certifications, any "live" issue that previously existed has been removed from this case because is not seeking approval for its ANDA until after February 28, 2023, which is the date on which the last of the five patents at issue expires. Plaintiffs respond first by asserting that Defendant's motion must be denied because Defendant is not permitted to change its Paragraph IV certification to a Paragraph III certification. Plaintiffs point to 21 C.F.R. 314.94, which states in the relevant part:

> A certification submitted under paragraphs (a)(12)(i) through (a)(12)(iii) of this section may be amended at any time before the effective date of the approval of the application. However, an applicant who has submitted a paragraph IV patent certification may not change it to a paragraph III certification if a patent infringement suit has been filed against another paragraph IV applicant unless the agency has determined that no applicant is entitled to 180–day exclusivity or the patent expires before the lawsuit is resolved or expires after the suit is resolved but before the end of the 180–day exclusivity period.

21 C.F.R. 314.94(a)(12)(viii). It appears that this regulation was originally put in place to prevent another Paragraph IV ANDA applicant from circumventing a first applicant's 180-day exclusivity period by amending a Paragraph IV certification to a Paragraph III certification after a patent was declared invalid. *See* 59 Fed. Reg. 50338 (Oct. 19, 1994) ("[T]he protection offered by 180-day exclusivity should not be undermined by changes from paragraph IV certification … [T]he agency has required that a patent remain on the list after being declared invalid or unenforceable until the end of any applicable 180-day exclusivity period… [W]here there is a patent that has been challenged by a paragraph IV applicant, a subsequent applicant will not be able to file a certification that there is no relevant patent or seek an immediately effective approval until either the patent or the 180-day exclusivity period expires.").

Defendant argues, however, that subsequent changes to 21 U.S.C. § 355 have rendered this regulation "irrelevant." Defendant notes that as a result of amendments in 2003 under the Medicare Modernization Act, any first applicant's 180-day exclusivity is automatically forfeited upon expiration of all the Orange Book-listed patents. *See* 21 U.S.C. §355(j)(5)(D)(i)(VI). As a result, a later applicant who has amended all their Paragraph IV certifications to Paragraph III certifications can no longer enter the market prior to the end of the first applicant's 180 days of exclusivity, as that 180 days of exclusivity is forfeited at the same time as the approval of the later applicant's ANDA—*i.e.*, the day the last Orange Book patent expires. *See* 21 U.S.C. § 355(j)(5)(B)(ii) ("If the applicant made a [Paragraph III certification], the approval may be made effective on the date certified under subclause (III).") Thus, in light of Defendant's Paragraph III certifications, Defendant's ANDA application cannot be approved until any 180-day exclusivity periods have been forfeited.

The Court finds Defendant's argument persuasive. The applicability and purpose of 21 C.F.R. 314.94(a)(12)(viii) appears to have been negated by the changes to § 355. Indeed, as Defendants point out, courts have recognized generic applicants' amendments of Paragraph IV certifications to Paragraph III certifications and allowed parties to stipulate to dismissal of a case based on such amendment. *See Pfizer, Inc. v. Anchen Pharm., Inc.*, Consolidated Civ. Action No. 12-808, Docket Entry No. 32; *Pfizer Inc. v. Apotex, Inc.*, Consolidated Civ. Action No. 12-808, Docket Entry No. 132; *Depomed, Inc. v. Impax Labs., Inc.*, Civ. Action No. 12-2154, Docket Entry No. 82. Plaintiffs, on the other hand, who bear the burden of establishing jurisdiction here, have pointed to no evidence that FDA has applied 21 C.F.R. 314.94(a)(12)(viii) to an ANDA for a reference-listed drug, where the first-filer filed their ANDA after the relevant 2003 Medicare Modernization Act provisions took effect. The Court, therefore, rejects Plaintiffs' argument that this regulation forecloses a finding of mootness here.

The Court also rejects Plaintiffs' argument that Defendant's "voluntary cessation of infringing activity" fails to render the matter moot "because [Defendant] is free to change its certification back to Paragraph IV at any time." Pl. Br. at 1. This is a Hatch-Waxman case, based upon a statutory scheme pursuant to which the filing of a Paragraph IV certification constitutes a "highly artificial" act of infringement. *See Eli Lilly & Co., supra.* As explained by the Federal Circuit, the enactment of § 271(e)(2) provided a "new" and "specialized" cause of action that enables court to "promptly resolve infringement and validity disputes before the ANDA applicant had engaged in the traditional statutorily defined acts of infringement." *AstraZeneca Pharmaceuticals LP v. Apotex Corp.*, 669 F.3d 1370, 1377 (Fed. Cir. 2012). As such, the factual scenario in this case is far different than those cases relied upon by Plaintiffs

in support of its argument, as those cases involve defendants that have engaged or may engage in a repeated course of wrongful conduct, *e.g.*, the discharge of mercury on multiple occasions in excess of the limits in an environmental permit or a proposed hiring practice that would be applied to multiple job applications. *See Davis*, 440 U.S. 625, *supra*; *Friends of the Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 120 S.Ct. 693 (2000). Here, Defendants have not engaged in any conduct other than the filing of a Paragraph IV certification, which has now been effectively withdrawn. This single, "highly artificial" act of alleged infringement hardly constitutes a "challenged practice" as found in the cited cases. *Friends of the Earth, Inc.*, 528 U.S. at 170.

Furthermore, under this Hatch-Waxman statutory scheme, the remedy for a prevailing plaintiff is an injunction delaying approval of a defendant's ANDA until expiration of all listed Orange Book patents. Defendant's amendment effectively gives Plaintiffs the relief that would have been available to them were this case to proceed.

Plaintiff next argues that this Court retains jurisdiction because Plaintiffs have asserted counterclaims for a declaratory judgment that the relevant patents are not infringed and are invalid. However, as discussed above, as no case or controversy exists to support Plaintiff's infringement claims, it follows that no case or controversy exists to support reciprocal declaratory judgment claims by Defendant.

Finally, Plaintiffs assert that Defendant's motion should be denied because Plaintiffs' request for attorney fees "is an independent basis for the Court's jurisdiction." Pl. Br. at 7. However, whether the Court may hear any subsequent request for attorney fees under 35 U.S.C. § 285 has no bearing on the specific issue to be decided with respect to Defendant's

motion, *i.e.*, whether the causes of action asserted in this action have been rendered moot. As Plaintiffs' themselves note, their request for attorney fees is not a cause of action in this case:

> A request under Section 285 is not a separate cause of action. "[R]ather a party pleading 'exceptional case' is simply **noting its intention to move for attorney fees, at the conclusion of the case**, pursuant to 35 U.S.C. § 285." *Nycomed U.S. Inc. v. Glenmark Generics Ltd.*, No. 8-cv-5023, 2010 WL 1257803 at *3 (E.D.N.Y. Mar. 26, 2010).

Pl. Br. at 9 (emphasis added). Although the merits of a Section 285 motion appear dubious here, the fact that Plaintiffs have in their complaint "noted their intention" to seek such relief does not preclude dismissal of this action as moot.

In sum, Defendant no longer seeks approval of its ANDA until after expiration of all the applicable patents. As such, Defendant cannot sell a drug product under its ANDA that would infringe Plaintiffs' patents. Consequently, there is no longer a case or controversy between the parties; the matter is moot. The Court lacks jurisdiction to continue this matter, and, therefore, grants Defendant's motion to dismiss.

III. CONCLUSION

For the reasons above, Defendant's motion to dismiss this matter without prejudice is granted. An appropriate Order accompanies this Opinion.

/s/ JOEL A. PISANO
United States District Judge

Dated: June 9, 2014